K102803

NOV 23 2011

510(k) Summary

Submitter:	HAMILTON MEDICAL AG Via Crusch 8 7402 Bonaduz, Switzerland
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Preparation Date:	2011-11-02
Trade Name:	HAMILTON-G5
Common Name:	Continuous Ventilator
Classification Name:	Ventilator, Continuous, Facility Use (21 CFR 868.5895, Product Code: CBK)
Legally marketed devices to which equivalence is being clamed:	HAMILTON-C2 (K092148) HAMILTON-GALILEO (K080181) Dräger EvitaXL with NeoFlow and SpO2 options (K072412, K983219) ARM PYTON ETT Cuff Pressure Regulator (K092733) GE Datex-Ohmeda Engström Carestation (K081842)

Device Description

The HAMILTON-G5 is an electronically controlled pneumatic intensive care ventilator ventilation system.

It uses oxygen and air or heliox to ventilate adults, pediatrics, infants, and neonates. It is powered by ac with battery backup to protect against power failure or unstable power and to facilitate intrahospital transport.

The HAMILTON-G5's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.

The user interface consists of a LCD-display with touch screen, keys, and a press-and-turn knob.

The new nebulization function with AERONEB nebulizers is for use with mechanically ventilated patients to aerosolize physician prescribed medications for inhalation. The new cuff pressure controller implemented in the HAMILTON-G5 is for continuous monitoring and adjustment of the cuff pressure of a tracheal or tracheostomy tube. nCPAP-PS is a new ventilation mode which applies nCPAP with additional pressure support by nasal interfaces with reduced dead space on neonates. NIV-ST is a new mode available for adult and pediatric patients. It delivers

pressure-controlled, time-cycled mandatory breaths and pressure-supported, flow-cycled spontaneous breaths by a mask or other noninvasive patient interface.

Intended use

The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital-type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment.

The device is not intended for transportation outside the hospital or for use in the home environment.

In the USA, federal law restricts this device to sale by or on the order of a physician.

SUMMARY OF THE TECHNOLOGY AND PERFORMANCE SPECIFICATIONS COMPARISON WITH THE PREDICATED DEVICES

The indication statements for the HAMILTON-G5 ventilator are comparable to those for the predicate devices.
Technological characteristics and performance specifications of the HAMILTON-G5 ventilator are substantially equivalent to those of the predicate devices.
The new nebulization function is comparable to the nebulization function in the predicate device Engström Carestation.
The new cuff pressure controller is considered to be substantial equivalent to the PYTON ETT Cuff Pressure Regulator.
The new NIV-ST mode is equivalent to the NIV-ST mode in the HAMILTON-C2 and the new nCPAP-PS mode can be compared with the PCV+/Assist, mask ventilation mode of the Evita XL.
HAMILTON MEDICAL has demonstrated the modified HAMILTON-G5 ventilator to be safe and effective. The ventilator is considered to be substantial equivalent to currently marketed predicate devices which have been previously cleared by FDA.

SUMMARY OF NON-CLINICAL PERFORMANCE TESTS

Safety testing of the HAMILTON-G5 with the new options was conducted according to IEC60601-1, IEC60601-1-2, IEC 60601-2-12 and other applicable standards. The test results show that the device is safe and effective for its intended use.

The ventilator was further subject to wave-form performance testing as described in the standard ASTM F1100-90. The data provided from these tests, were shown to be substantially equivalent to a legally marketed device.

The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted or required in support of this premarket clearance notification.

SUMMARY OF OTHER INFORMATION

This submission included comparison of intended use statements, proposed product labeling and summary information and labeling on predicate devices.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-G5 ventilator is as safe, as effective, and performs as well as or better than the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

HAMILTON MEDICAL AG
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NOV 23 2011

Re: K103803
Trade/Device Name: HAMILTON-G5
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 21, 2011
Received: November 22, 2011

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: HAMILTON-G5

Indication for Use: The HAMILTON-G5 ventilator is intended to provide positive pressure ventilatory support to adult and pediatric patients, and optionally to infant and neonatal patients.
The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care, including use as a patient bedside for intra-facility transport, provided compressed gas is supplied.
The device is not intended for transportation outside the hospital or for use in the home environment.

Prescription Use ___X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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